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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,263	04/18/2006	Gerard M Housey	395/61	6621

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,263	HOUSEY ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/8/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II (claims 16-17) in the reply filed on 1 December 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1 December 2008.

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Claim Objections

Claims 16 and 17 are objected to because of the following informalities: claims 16 and 17 use the acronym "IRS2" without first defining what it represents in the independent claims. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16 and 17 are indefinite because the claims do not have a step that clearly relates back to the preamble. For example, there is no step indicating how measuring the amount of IRS2 binding protein bound to IRS2 relates back to the goal of determining whether a small molecule is an activator or inhibitor of IRS2 (claim 16). In addition, there is no step indicating whether an increase in reproter protein level in the Test Cell has occurred relates back to the goal of identifying a small molecule capable of increasing the level of expression from and IRS2 promoter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,858,701 (issued 12 January 1999; on Applicants' 1449 form—hereafter "the '701 patent").

The '701 patent teaches a two-phase method for evaluating a treatment for the ability of the treatment to inhibit or promote IRS2 metabolism, or to evaluate test compounds for use as therapeutic agents. The method includes: an in vitro phase in

which the test compound is contacted with a cell which includes a reporter gene functionally linked to an IRS2 regulatory sequence (i.e., promoter), and detecting the modulation of the expression of the reporter gene (see column 7, lines 11-27). In other words, the '701 patent teaches the exact method recited in claim 17, namely contacting a test cell which contains an IRS2 promoter linked to a reporter gene and detecting changes in expression. The phrase "such that increased expression of the IRS2 promoter sequence using a substance known to be capable of up-regulating the endogenous IRS2 gene results in an increase in reporter protein levels" merely reports the result, i.e., a substance that increases expression of IRS2. The '701 patent teaches testing a substance that could either increase or decrease expression of IRS2, thus encompasses all of the limitations of claim 17.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,858,701 (on Applicants' 1449 form—cited above as "the '701 patent") in view of U.S. Patent No. 5,688,655 (issued 18 November 1997; on Applicant's 1449 form—hereafter "the '655 patent"). The first factor to consider when making a rejection under 35 U.S.C. 103(a) is to determine the scope and contents of the prior art. The '701 patent teaches a drug screening method wherein a preparation of cells that "misexpresses" IRS2 (see, for example, column 4, lines 55-67 to column 5, lines 1-10; column 6, lines 41-57) is used. Note that "misexpression" is defined at column 11, lines 58-60 as including over-expression compared to wild type. The '701 patent further teaches that a given substance or treatment is administered to said test cell or organism which misexpresses IRS2 and then the effect of the substance or treatment on an aspect of IRS2 metabolism is evaluated. For example, an effect on an aspect of IRS2 metabolism is defined as including evaluating a change in the level of IRS2 binding

activity (see column 6, lines 41-57). The '701 patent further teaches a method for evaluating a compound for the ability to modulate (e.g. to inhibit or promote) the binding of IRS2 polypeptide with an IRS2 binding ligand, e.g., the insulin receptor (see column 6, lines 62-67 through column 7, lines 1-10). In the case of an IRS2 polypeptide the method includes: (i) combining an IRS2 polypeptide, an IRS2 binding ligand and a compound; and (ii) detecting the formation of a complex which includes the IRS2 polypeptide and the IRS2 binding ligand. Modulation of the formation of the complex in the presence of the compound (e.g., as compared with formation in the absence of the compound) is indicative of a modulation of the interaction between an IRS2 polypeptide and an IRS2 binding ligand (see column 6, lines 62-67 through column 7, lines 1-10). In summary, the '701 patent teaches a method of determining whether a compound promotes (i.e., activates) or inhibits binding of an IRS2 receptor (i.e., an IRS2-binding protein) to IRS2 by administering the compound to the test cells which "misexpress" (over-express) IRS2 and measuring the binding activity.

The second factor to consider when making a rejection under 35 U.S.C. 103(a) is to ascertain the differences between the prior art and the claims at issue. The '701 patent does not explicitly teach comparison of the results from a test cell population that over-express IRS2 to a control cell population that produce IRS2 at a lower level (or not at all). The '655 patent teaches a method of determining whether a substance is an inhibitor or an activator of a protein, which comprises: a) providing a test cell which overproduces a selected protein relative to a control cell which produces said protein at a lower level (or not at all), and wherein production of said protein in said test cell

evokes a responsive change in a phenotypic characteristic, b) treating said test cell containing the overproduced selected protein with said substance, and c) examining the treated test cell to determine whether it exhibits a change in said phenotypic characteristic in response to said substance, wherein the examination for a change in phenotypic characteristic in response to said substance includes comparing the response of the treated cell to a comparably treated test cell which does not overproduce the selected protein (see, for example, claims 1-3 of the '655 patent). In summary, the '655 patent teaches a template of drug screening in which a test cell population that over-expresses a protein of interest, or POI is contacted with a test substance and the results are compared to a control cell population that produces the POI at a lower level (or not at all). The '655 patent explicitly teach this extra step of comparison of effect in a cell population that does not over-express the POI.

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The skill in the art of drug screening is high, and in fact, Applicants point to the methods of the '655 patent in their specification as a template for the claimed drug screening methods at paragraph [0046] of the instant specification: "cell-based assay systems capable of being adapted specifically for the examples which follow below have been previously developed by Applicants (See, for example, U.S. Pat. No. 5,688,655)." Applicants clearly point to the '655 patent as evidence that the encompassed drug screening methods were previously developed. This segues into the final factor to be considered, which is to consider the objective evidence present in the application indicating obviousness or nonobviousness. Since the instant application points to the '655 patent as a template for drug screening methods, this does not suggest that there

are any surprising or unexpected results in the claimed methods. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of the '701 patent by comparing results of the screening tests therein described to a cell population that produces IRS2 protein at a lower level (or not at all), as taught in '655 patent because the '655 patent teaches that their method "combines the rapidity and ease of performance of the soft agar assay with a specificity for detecting an active agent exceeding that of the morphology assay. In brief, the method which [described] herein involves the generation of a cell line purposefully engineered to detect both stimulatory and inhibitory agents which are absolutely specific ***for any given protein which affects the cultural or morphological characteristics of the cell***." (See column 2, lines 29-37; emphasis added by the Examiner). The person of ordinary skill in the art would have been motivated because the methods of the '655 patent provide "a rapid, yet powerful screening system for the discovery and identification of both inhibitors and activators of proteins…[that] may be applied to virtually any type of protein…" (See column 2, lines 49-53). Furthermore, for these reasons as well, the person of ordinary skill in the art could have reasonably expected success. Thus, the claims do not contribute anything non-obvious over the prior art.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. A definition of "regulatory sequence" is provided to show that it

encompasses "promoter"; a DNA sequence involved in regulating the expression of a gene; for example, a promoter or operator (from Principles of Biochemistry, 2nd Ed., Lehninger, 1993; p. G-13).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649